REMARKS

Applicants respectfully request entry of the foregoing and reconsideration of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.112, and in light of the remarks which follow.

Claims 1-47 are pending in the application, new claims 18-47 having been added above.

By the above amendments, claims 1-6 have been amended by deleting the word "intimate" to address the §112 issue raised with respect to these claims. Claims 1-6 have been further amended to specify that the vitamins A, C, E and zinc and selenium are the only active agents in the composition for promoting hair regrowth and/or retarding hair loss, increasing the mean diameter of strands of hair, decreasing the heterogeneity of the diameters of strands of hair, increasing hair density, improving the quality and/or appearance of a head of hair and inducing repigmentation of the hair, respectively. Claim 12 is amended to address the §112 issue, by amending the claim in accordance with the disclosure at page 7, paragraph 47 of the specification to read, in part, "a synthetic molecule exhibiting enzymatic activity which mimics a peroxidase." Claim 13 has been amended to address the §112 issue, by deleting the word "any." Finally, claim 14 has been amended in accordance with the Examiner's suggestion to read, in part, "wherein the vitamin A is a beta carotene." Additionally, Applicants have added new claims 18-47 to further define exemplary embodiments of the present invention. New claims 18-23 correspond to original claims 1-6 except that they incorporate the amounts of ingredients defined in original claim 7. New claims 24-29 correspond to claims 18-23 but add the

further recitation that the composition is formulated in a tablet. New claims 30-35 correspond to original claims 1-6, but include the further recitation that the composition is a topical anti-hair-loss composition. Support for new claims 24-35 can be found at least at page 9, paragraph 55 and page 8, paragraph 50. New claims 36-41 correspond to original claims 1-6, except that they include the further recitation that the vitamin A, C, E, zinc and selenium are the only active vitamins and metals in the composition. Finally, new claims 42-47 correspond to new claims 24-29 except that they define the composition as being formulated for oral administration.

Applicants thank the Examiner for the courtesies extended to their representative during the personal interview of March 27, 2003. In particular, Applicants thank the Examiner for acknowledging that the above amendments would overcome the outstanding §112 rejections.

Turning now to the Official Action, Applicants acknowledge that the Examiner has made the Restriction Requirement final. However, Applicants submit that where product and process claims are presented in the same application, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all of the limitations of an allowed product claim. See MPEP §821.04. Because process claim 17 includes all of the limitations of elected product claim 1, process claim 17 must be rejoined with the product claims once the product claim is found to be allowable.

Additionally, Applicants wish to address the statement at page 4 of the Official Action, which asserts that "... Applicant's arguments that the 'intimate admixture' of

ingredients is a critical feature of the claimed invention in Paper No. 5 ('Response to Restriction Requirement', page 2, lines 8-14)." In particular, Applicants submit that despite this assertion, none of the remarks in the Response to Restriction Requirement, including the remarks at page 2, lines 8-14, state that the intimate admixture of recited ingredients is "a critical feature of the claimed invention."

Claims 1-16 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. For at least the reasons that follow, withdrawal of the rejection is in order.

With respect to the rejection of claims 1-6 for including the phrase "intimate admixture," Applicants have amended claims 1-6 to obviate the rejection. That is, Applicants have deleted the word "intimate" and inserted the word --an-- so that the claims read, in part, "a thus effective amount of an admixture...."

With respect to the rejection of claim 8 for including a typographical error, because the Examiner agreed during the personal interview that the rejection was intended to be directed to claim 13, Applicants amended claim 13 to obviate the rejection. Specifically, Applicants deleted the word "any" to obviate the rejection.

With respect to the rejection of claim 12 for including the phrase "a synthetic molecule or association exhibiting enzymatic activity," Applicants amended claim 12 to obviate the rejection. That is, Applicants amended claim 12, in accordance with the disclosure at page 7, paragraph 47, of the specification, to read "a synthetic molecule exhibiting enzymatic activity which mimics a peroxidase."

With respect to the rejection of claim 14, for use of the phrase "vitamin A being present as beta-carotene equivalent thereof," Applicants have amended claim 14 to obviate

the rejection. In particular, Applicants have amended claim 14 in accordance with the Examiner's suggestion to read "wherein the vitamin A is a beta-carotene."

Finally, with respect to the rejection of claim 15 for failing to provide clear antecedent basis for "beta-carotene," it was agreed during the personal interview that in view of the amendments to claim 14, no amendments to claim 15 would be needed.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the §112 rejections of claims 1-16.

Claims 1-7, 9, 11 and 14-16 stand rejected under 35 U.S.C. §102(b) as being anticipated by Drug Launches. For at least the reasons that follow, withdrawal of the rejection is in order.

The present invention relates to novel compositions based on vitamins and on inorganic/organic metal salts for promoting regrowth of the hair and/or decreasing hair loss and/or improving quality of the hair and/or promoting repigmentation thereof. See specification at page 1, paragraph 2.

For example, independent claims 1-6, as amended above, are directed to cosmetic/pharmaceutical compositions for promoting hair regrowth and/or retarding hair loss, increasing the mean diameter of strands of hair, decreasing the heterogeneity of the diameters of strands of hair, increasing hair density, improving the quality and/or the appearance of a head of hair, and inducing repigmentation of the hair, the compositions comprising effective amounts of an admixture of vitamin A, vitamin C, vitamin E, and zinc and selenium values, wherein the vitamin A, vitamin C, vitamin E, zinc and selenium are the only active agents in the composition for achieving the recited purposes.

Drug Launches is directed to the Ocuvite® composition for treatment and maintenance of ocular health. The Ocuvite® composition comprises zinc oxide, copper oxide, vitamin C, vitamin E, vitamin A and selenium.

It is well established that in order to demonstrate anticipation under 35 U.S.C. §102(b), each element of the claim in issue must be found, either expressly described or under principles of inherency, in a single prior art reference. See Kalman v. Kimberly-Clark Corp., 218 U.S.P.Q. 789 (Fed. Cir. 1983). That is not the case here.

For example, the compositions of claims 1-6 comprise an admixture of vitamin A, C, E and zinc and selenium values in amounts effective to promote hair regrowth and/or retard hair loss, increase the mean diameter of strands of hair, decrease the heterogeneity of diameters of strands of hair, increase hair density, improve the quality and/or appearance of a head of hair and repigmentation of the hair, respectively. In contrast, however, Drug Launches fails to disclose or fairly suggest that the amounts of ingredients in the disclosed composition should, or even could, be effective to achieve the hair-related purposes defined in claims 1-6. That is, Applicants submit that the amounts of ingredients in Ocuvite® are neither disclosed nor suggested as being effective to promote hair regrowth and/or retard hair loss, increase the mean diameter of strands of hair, decrease the heterogeneity of the diameters of strands of hair, increase hair density, improve the quality and/or the appearance of a head of hair or to induce repigmentation of the hair.

In fact, the Bausch & Lomb facsimile relied on in support of the §102 rejection, reveals that the amounts of ingredients disclosed in Drug Launches do not represent the actual amounts of ingredients present in the composition itself, but rather represent

Label/Claim amounts. That is, the Bausch & Lomb facsimile indicates that the actual (i.e., the Quantity/Tablet) amounts are as follows: vitamin A (as beta carotene) 20.250 mg, vitamin C (as ascorbic acid) 74 mg, vitamin E (as dl-α-tocopheryl acetate) 66 mg, zinc (zinc oxide) 54.767 mg and selenium (sodium selenate) 0.144 mg. Accordingly, Applicants submit that the amounts of relevant ingredients in Ocuvite® are outside of the effective ranges disclosed at page 7, paragraph 44, of the specification. As a result, Applicants submit that the amounts of relevant ingredients actually present in Ocuvite® would not be effective to achieve the purposes defined in claims 1-6. Thus, Applicants submit that the compositions of claims 1-6 are not anticipated by Ocuvite®.

Furthermore, Applicants submit that the Official Action has failed to establish that the Bausch & Lomb facsimile is a proper prior art reference. That is, MPEP §2128 states that in order for a printed publication to constitute prior art, the document must have been "disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." MPEP §2128 further requires that "one who wishes to characterize the information, in whatever form it may be, as a "printed publication" *** should produce sufficient proof of its dissemination or that it has otherwise been available and accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents." A copy of MPEP §2128 is attached hereto for the Examiner's convenience.

Because the Official Action fails to provide any evidence whatsoever to demonstrate that the Bausch & Lomb facsimile constitutes a proper "printed publication" under §2128, Applicants submit that the reliance on this document as prior art is improper. Thus, the

rejection of the claimed composition comprising vitamin A as beta-carotene as being anticipated by Drug Launches in view of the Bausch & Lomb facsimile is improper and should be withdrawn.

For at least these reasons, the compositions of claims 1-6 are not anticipated by Drug Launches. Applicants respectfully request reconsideration and withdrawal of the §102(b) rejection of claims 1-7, 9, 11 and 14-16.

Claims 1, 7, 8 and 10-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kronnie (DE 197 57 921 (DE '921)) in view of Cauwenbergh (U.S. Patent No. 6,099,870), Proctor (U.S. Patent No. 6,150,405) and Nishida (JP 06256142). For at least the reasons that follow, withdrawal of the rejection is in order.

Kronnie discloses a composition, which the Official Action itself admits, does not contain selenium. Furthermore, the composition of *Kronnie* includes numerous components such as, for example, cannabis sativa, vitamin B12, collagen, etc., in addition to vitamins A, C, E and zinc. Accordingly, Applicants submit that no person of ordinary skill in the art would have been motivated by *Kronnie* to select only vitamin A, C, E and zinc and selenium from the numerous components disclosed and to combine those components with selenium to arrive at the composition of claims 1-6, which define vitamin A, C, E and zinc and selenium as the only active agents.

Additionally, the only Example in *Kronnie* is directed to a shampoo comprising, among various other ingredients, 2 g of vitamin A, 3 g of vitamin E and 2 g of vitamin C. Thus, Applicants submit that the composition of *Kronnie* fails to disclose or fairly suggest

using the effective amounts of vitamin A, C, E and selenium defined in claims 1-6 and disclosed, for example, at page 7, paragraph 44 of the specification.

The secondary references fail to overcome the above deficiencies of *Kronnie*. For instance, *Cauwenbergh* is substantially directed to a method of increasing the amount of anagen hair by applying an azole or zinc pyrithione. Furthermore, the objective of *Cauwenbergh* is to inhibit the growth of P. ovale. Thus, while *Cauwenbergh* mentions the possibility of using selenium sulfide, *Cauwenbergh* fails to provide even a single Example directed to the use of selenium sulfide. Instead, the tested compositions of *Cauwenbergh* contain either ketoconazole or zinc pyrithione, and indicate a preference for zinc pyrithione.

Clearly, the mere mention of selenium sulfide would not have been sufficient to motivate one of ordinary skill in the art to have modified the composition of *Kronnie* to include only vitamin A, C, E and zinc in the claimed effective amounts and to then add selenium in the defined effective amount to arrive at the compositions of claims 1-6. That is, because *Cauwenbergh* relies on activity related to inhibition of P. ovale, and because *Cauwenbergh* fails to disclose or suggest using the claimed effective amounts of relevant ingredients, Applicants submit that no person of ordinary skill in the art would have been motivated by *Cauwenbergh* to select only selenium and combine it with vitamin A, C, E and zinc disclosed in *Kronnie* to obtain the compositions of claims 1-6.

Proctor also fails to remedy the deficiencies of *Kronnie*. That is, *Proctor* relates to hair loss treatment with ascorbate.

Finally, *Nishida* also fails to overcome the above deficiencies of *Kronnie*. That is, *Nishida* relates to a hair tonic agent containing a ternary mixture of carotenes, lycopene and specific mono- or diglycerides. The tonic of *Nishida* can also contain hydroxy pyridone derivative and various plant extracts. However, it is clear from *Nishida* that the activity of the resulting tonic is based primarily on the basic ternary mixture. Furthermore, while numerous possible adjuvants are cited, *Nishida* fails to disclose or fairly suggest using selenium or vitamin C. Accordingly, Applicants submit that *Nishida*, even if combined with *Cauwenbergh*, *Proctor* and *Kronnie*, would not have motivated a person of ordinary skill in the art to arrive at the compositions of claims 1-6.

For at least these reasons, the compositions of claims 1-6 would not have been obvious over *Kronnie* in view of *Cauwenbergh*, *Proctor*, and *Nishida*. Applicants respectfully request reconsideration and withdrawal of the §103 rejection of claims 1, 7, 8 and 10-13.

Finally, Applicants have added new claims 18-47 to further define exemplary embodiments of the present invention. Applicants submit that the subject matter of claims 18-47 are also patentably distinguished from the cited references.

From the foregoing, Applicants earnestly solicit further and favorable action in the form of a Notice of Allowance.

If there are any questions concerning this paper or the application in general, Applicants invite the Examiner to telephone the undersigned at the Examiner's earliest convenience.

Respectfully submitted,

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ATTACHMENT: MPEP §2128

Attachment to Amendment dated April 7, 2003

Marked-up Claims 1 - 6 and 12 - 14

1. (Amended) A cosmetic/pharmaceutical composition for promoting hair regrowth and/or retarding hair loss, comprising a thus effective amount of [intimate] an admixture of vitamin A, vitamin C, vitamin E, and zinc and selenium values wherein the vitamin A, vitamin C, vitamin E, zinc and selenium are the only active agents in the composition for promoting hair regrowth and/or retarding hair loss.

2. (Amended) A cosmetic/pharmaceutical composition for increasing the mean diameter of strands of hair, comprising a thus effective amount of [intimate] an admixture of vitamin A, vitamin C, vitamin E, and zinc and selenium values wherein the vitamin A, vitamin C, vitamin E, zinc and selenium are the only active agents in the composition for increasing the mean diameter of strands of hair.

3. (Amended) A cosmetic/pharmaceutical composition for decreasing the heterogeneity of the diameters of strands of hair, comprising a thus effective amount of [intimate] an admixture of vitamin A, vitamin C, vitamin E, and zinc and selenium values wherein the vitamin A, vitamin C, vitamin E, zinc and selenium are the only active agents in the composition for decreasing the heterogeneity of the diameters of strands of hair.

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Marked-up Claims 1 - 6 and 12 - 14

4. (Amended) A cosmetic/pharmaceutical composition for increasing hair density, comprising a thus effective amount of [intimate] an admixture of vitamin A, vitamin C, vitamin E, and zinc and selenium values wherein the vitamin A, vitamin C, vitamin E, zinc and selenium are the only active agents in the composition for increasing hair density.

5. A cosmetic/pharmaceutical composition for improving the quality and/or the appearance of a head of hair, comprising a thus effective amount of [intimate] an admixture of vitamin A, vitamin C, vitamin E, and zinc and selenium values wherein the vitamin A, vitamin C, vitamin E, zinc and selenium are the only active agents in the composition for improving the quality and/or the appearance of a head of hair.

6. (Amended) A cosmetic/pharmaceutical composition for inducing repigmentation of the hair, comprising a thus effective amount of [intimate] an admixture of vitamin A, vitamin C, vitamin E, and zinc and selenium values wherein the vitamin A, vitamin C, vitamin E, zinc and selenium are the only active agents in the composition for inducing repigmentation of the hair.

12. (Amended) The cosmetic/pharmaceutical composition as defined by any of Claims 1 to 6, further comprising an additional antioxidant, a catalase, a peroxidase, a

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Marked-up Claims 1 - 6 and 12 - 14

synthetic molecule [or association] exhibiting enzymatic activity which mimics a peroxidase, a sulfur-containing amino acid, or combination thereof.

13. (Amended) The cosmetic/pharmaceutical composition as defined by [any] Claim 8, comprising about 1 mg of vitamin A, about 120 mg of vitamin C, about 30 mg of vitamin E, about 20 mg of zinc, and about 100 μg of selenium.

14. (Amended) The cosmetic/pharmaceutical composition as defined by any of Claims 1 to 6, wherein the vitamin A [being present as] is a beta-carotene equivalent thereof.